DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Medgyn Products, Inc.
Amar Agadi
Chief Medical Officer
100 W. Industrial Rd.
Addison, Illinois 60101

Re: K143669
Trade/Device Name: MedGyn Straight IUI Catheter, MedGyn Mini IUI Catheter, MedGyn Curved, Mini IUI Catheter
Regulation Number: 21 CFR 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: Class II
Product Code: MQF
Dated: October 20, 2015
Received: October 26, 2015

Dear Amar Agadi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143669

Device Name
MedGyn Straight IUI Catheter, MedGyn Mini IUI Catheter, MedGyn Curved,Mini IUI Catheter.

Indications for Use *(Describe)*

MedGyn IUI Catheters are used for the introduction of washed spermatozoa into the uterine cavity through the cervix.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

MedGyn IUI Catheters

(MedGyn straight IUI Catheter, MedGyn Mini IUI Catheter, MedGyn curved,mini IUI catheter)

This 510(k) Summary is provided in accordance with the requirements of 21 CFR 807.92

Prepared on: December 26, 2014

Submitter:

MedGyn Products, Inc.
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Contact Person :

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Device Trade Name:	MedGyn Straight IUI Catheter MedGyn Mini IUI Catheter MedGyn Curved,Mini IUI Catheter
Common Name:	Intrauterine Insemination (IUI) Cannula
Device Classification:	II
Classification Name	Assisted reproduction catheters
Product Code:	MFQ
Regulation Number:	21 CFR 884.6110

Predicate Devices:

510(K) Number: K954099
Product Name: Select IUI
Manufacturer: Select Medical Systems, Inc.

Device description:

MedGyn straight IUI, mini IUI, and curved, mini IUI catheters are used for intrauterine insemination for delivery of washed spermatozoa through the cervical os.

The straight IUI is composed of a 21.4 cm length tube with subparts consisting of a polyethylene tube connecting with a polypropylene tube. The outer diameter of the polyethylene tube is 2.1 mm. That of the polypropylene tube is 2.75 cm. The tube is connected proximally to an ABS connector for attachment to a syringe.

The mini IUI is exactly the same as the straight IUI except that the outer diameter of the inner polyethylene tube is 1.6 mm. The curved, mini IUI is exactly the same as the mini IUI except that it is slightly curved at its distal tip.

The materials used in this device are the same materials used in predicate devices. The combination of an inner polyethylene tube with an outer polypropylene tube is the exact same material and the same concept as that used in the “Select IUI” and “The Curve”, (K954099 and K012935, respectively). Additionally, the dimensions of the MedGyn IUI catheters are almost identical with those of the Select IUI and the Select “The Curve” catheters.

(Note syringe is not included with catheters)

Indications for Use:

MedGyn IUI Catheters are used for the introduction of washed spermatozoa into the uterine cavity through the cervix

Technological Comparison to Predicate Devices:

The indication for use and technology of the MedGyn IUI catheters are substantially equivalent to the identified predicate devices.

Table :1 Comparison of Predicates with MedGyn Candidate Device

Manufacturer	Select Medical Systems,Inc	MedGyn IUI Catheters comparison to predicate	Comparison of Predicate with MedGyn Candidate Device
510(k) Number	K954099	N/A	N/A
Product Code	MFD	MFD	Same
Regulation Number	884.5250	884.5250	Same
Regulation Name	Cannula, intrauterine insemination	Cannula, intrauterine insemination	Same
Anatomical Site	Uterine Cervix	Uterine Cervix	Same
Intended Use	Artificial insemination	Artificial insemination	Same
Where Used:	Physician's Office	Physician's Office	Same
Indications for use:	The Select IUI is used for intrauterine artificial insemination.	The MedGyn straight, mini, and curved,mini IUI catheters are to be used for the introduction of washed spermatozoa into the uterine cavity through the cervix.	Same
Overall Design	The Select IUI consists of an 20 cm in length catheter composed of an inner polyethylene tube and an outer polypropylene tube. the exposed polyethylene tube measures 4.5cm in length, and is located at the distal end of the catheter/cannula. The outer diameter of the polypropylene tube and polyethylene tube are 2.6 mm and 2.1 mm, respectively. The distal tip has two side holes. There are six (6) colored graduation marks each cm from the distal tip of the catheter starting at 5 cm and ending at 10 cm. A syringe is not included with the products.	The MedGyn straight, mini, and curved,mini IUI catheters are each 21.4 cm in length. The straight catheter has a proximal tube with outer diameter of 2.75 mm and length of 16.4 cm. The distal tube has an outer diameter of 2.1 mm and is 5 cm in length. The mini IUI catheter has a proximal tube outer diameter of 2.75 mm with a length of 16.4 cm and a distal tube outer diameter of 1.6 mm of length 5 cm. the curved, mini IUI catheter has a proximal tube length of 16.4 cm with an outer diameter of 2.75 mm with a distal tube outer diameter of 1.6 mm of length 5 cm. The distal 3mm aspect of this tube is slightly curved for insertion into a variably-positioned uterus (retroverted, etc.). All catheters are smooth in texture down to the tip. The straight catheter has two side holes at the tip. The mini and curved, mini catheters have a single hole at the tip.	The MedGyn cannula/catheter is approximately 1.4 cm longer, and the outer diameter is approximately .15 mm larger. The distal inner tubes are the same

The comparison of the above mentioned in Table 1 the predicates devices the outer diameter IUI straight is 2.6mm and 2.1mm respectively, the curved 2.6mm and 1.6mm in diameter. The MedGyn cannula/catheter is approximately 1.4 cm longer, and the outer diameter is approximately .15 mm larger. The distal inner tubes are the same. The differences in dimensions between the subject and predicate device do not raise different questions of safety and effectiveness.

Summary of Performance Testing:

Stability testing was conducted in accordance with ASTM F1980-07 (accelerated aging) to substantiate a shelf life of 1 year.

Mouse Embryo Assay (MEA) testing was conducted on each version of the MedGyn IUI catheters.

Endotoxin Testing (LAL) was conducted per USP <85> for each version of the MedGyn IUI catheters.

Human Sperm Survival Assay (HSSA) testing has been performed on the device the test results shows that the motility remained consistent, both the test and control samples showed no sign of affecting motility during the course of the assay.

The biocompatibility of the device includes cytotoxicity, Intracutaneous Reactivity and sensitization of the final device tests were performed on the IUI device;

a. Cytotoxicity: Microscopic evaluation of the cells showed that the extract from the test article received a cytotoxicity grade of '0' at 24 ± 3, 48 ± 3 and 72 ± 3 hours and was considered Non-Cytotoxic.

b. Intracutaneous Reactivity: The USP 0.9% Sodium chloride for injection (NaCl) and Cottonseed Oil (CSO) extracts of the test article, IUI catheters, were evaluated for their potential to produce irritation after intracutaneous injection in white rabbits. The test article sites did not show a significantly greater biological reaction than the sites injected with the control article.

c. Skin Sensitization: A comparison of the biological responses seen following guinea pig sensitization of the test item extracts and solvents were reported and interpreted, results of

the IUI Catheter did not show any sensitization reactions..

The above test reports data proven that device is safe for the use.

Substantially Equivalent Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared with the predicate device.

The MedGyn IUI Catheters are substantially equivalent to the proposed predicate device.